

Claims

1. A pharmaceutical formulation adapted for intra-muscular injection comprising fulvestrant, 30% or less weight of a pharmaceutically-acceptable alcohol per volume of formulation, at least 1% weight of a pharmaceutically-acceptable non-aqueous ester solvent miscible in a ricinoleate vehicle per volume of formulation and a sufficient amount of a ricinoleate vehicle so as to prepare a formulation which is capable after injection of attaining a therapeutically significant blood plasma fulvestrant concentration of at least  $2.5\text{ngml}^{-1}$  for at least 2 weeks.
- 10 2. A pharmaceutical formulation as claimed in claim 1 wherein the blood plasma fulvestrant concentration is attained for at least 4 weeks.
3. A pharmaceutical formulation as claimed in claim 1 wherein the blood plasma fulvestrant concentration is attained for 2 to 5 weeks.
- 15 4. A pharmaceutical formulation adapted for intra-muscular injection comprising fulvestrant, 30% or less weight of a pharmaceutically-acceptable alcohol per volume of formulation, at least 1% weight of a pharmaceutically-acceptable non-aqueous ester solvent miscible in a ricinoleate vehicle per volume of formulation and a sufficient amount of a ricinoleate vehicle so as to prepare a formulation of at least  $45\text{mgml}^{-1}$  of fulvestrant.
- 20 5. A pharmaceutical formulation as claimed in claim 1 to 4 which contains 25% w/v or less of a pharmaceutically-acceptable alcohol.
6. A pharmaceutical formulation as claimed in claim 5 which contains 20% w/v or less of a pharmaceutically-acceptable alcohol.
- 25 7. A pharmaceutical formulation as claimed in any claim from 1 to 6 which contains 60% w/v or less of a pharmaceutically-acceptable non-aqueous ester solvent.
- 30 8. A pharmaceutical formulation as claimed in claim 7 which contains 50%w/v or less of a pharmaceutically-acceptable non-aqueous ester solvent .

9. A pharmaceutical formulation as claimed in claim 7 which contains 45% w/v or less of a pharmaceutically-acceptable non-aqueous ester solvent.

5 10. A pharmaceutical formulation as claimed in claim 7 which contains 40% w/v or less of a pharmaceutically-acceptable non-aqueous ester solvent.

11. A pharmaceutical formulation as claimed in claim 7 which contains 35% w/v or less of a pharmaceutically-acceptable non-aqueous ester solvent.

10 12. A pharmaceutical formulation as claimed in claim 7 which contains 30% w/v or less of a pharmaceutically-acceptable non-aqueous ester solvent.

13. A pharmaceutical formulation as claimed in claim 7 which contains 25% w/v or less of a pharmaceutically-acceptable non-aqueous ester solvent.

15 14. A pharmaceutical formulation as claimed in any claim from 1 to 13 wherein the pharmaceutically-acceptable alcohol is a mixture of ethanol and benzyl alcohol.

20 15. A pharmaceutical formulation as claimed in any claim from 1 to 14 wherein the pharmaceutically-acceptable non-aqueous ester solvent is selected from benzyl benzoate, ethyl oleate, isopropyl myristate, isopropyl palmitate or a mixture of any thereof.

16. A pharmaceutical formulation as claimed in any claim from 1 to 15 wherein the pharmaceutically-acceptable non-aqueous ester solvent is benzyl benzoate.

25 17. A pharmaceutical formulation as claimed in any claim from 1 to 16 wherein the total volume of the formulation is 6ml or less, and the concentration of fulvestrant is at least 45mgml<sup>-1</sup>.

18. A pharmaceutical formulation as claimed in any claim from 1 to 13 wherein the total amount of fulvestrant in the formulation is 250mg, or more, and the total volume of the formulation is 6ml, or less.

5 19. A pharmaceutical formulation as claimed in claim 18 wherein the total amount of fulvestrant in the formulation is 250mg and the total volume of the formulation is 5 to 5.25ml.

10 20. A pharmaceutical formulation as claimed in any of claims 1-19 wherein the pharmaceutically-acceptable alcohol is a mixture of 10% weight of ethanol per volume of formulation, 10% weight of benzyl alcohol per volume of formulation and 15% weight of benzyl benzoate per volume of formulation and the ricinoleate vehicle is castor oil.

15 21. A method of treating a benign or malignant disease of the breast or reproductive tract by administration to a human in need of such treatment by intramuscular a pharmaceutical formulation as claimed in claims 1 to 19.

22. A method as claimed in claim 21 for treating breast cancer.

20 23. A syringe or vial containing a pharmaceutical formulation as defined in claim 20.

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